Health Canada
Pest Management Regulatory Agency

Santé Canada
Agence de réglementation de la lutte antiparasitaire

**ERC2007-02**

## EVALUATION REPORT

# *Sclerotinia minor* strain IMI 344141

*(publié aussi en français)*

**22 June 2007**

**This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:**

**Publications**
**Pest Management Regulatory Agency**
**Health Canada**
**2720 Riverside Drive**
**A.L. 6605C**
**Ottawa, Ontario**
**K1A 0K9**

**Internet:** pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
**Facsimile: 613-736-3758**
**Information Service:**
**1-800-267-6315 or 613-736-3799**
pmra_infoserv@hc-sc.gc.ca

Canada

ISBN: 978-0-662-46274-3 (978-0-662-46275-0)
Catalogue number: H113-26/2007-2E (H113-26/2007-2E-PDF)

**© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2007**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

# TABLE OF CONTENTS

OVERVIEW ..... 1
Registration Decision for *Sclerotinia minor* strain IMI 344141 ..... 1
What Does Health Canada Consider When Making a Registration Decision? ..... 1
What Is *Sclerotinia minor* strain IMI 344141? ..... 2
Health Considerations ..... 2
Environmental Considerations ..... 4
Value Considerations ..... 5
Measures to Minimize Risk ..... 5
What Additional Scientific Information Is Required? ..... 6
Other Information ..... 6

SCIENCE EVALUATION ..... 7

1.0 The Active Ingredient, Its Properties and Uses ..... 7
1.1 Identity of the Active Ingredient ..... 7
1.2 Physical and Chemical Properties of the Active Substances and End-use Products ..... 8
1.3 Directions for Use ..... 9
1.4 Mode of Action ..... 9

2.0 Methods of Analysis ..... 10
2.1 Methods for Identification of the Microorganism ..... 10
2.2 Methods for Establishment of Purity of Seed Stock ..... 10
2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products ..... 11
2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites ..... 11
2.5 Methods for Determination of Relevant Impurities in the Manufactured Material ..... 11
2.6 Methods to Show Absence of Any Human and Mammalian Pathogens ..... 11
2.7 Methods to Determine Storage Stability, Shelf-Life of the Microorganism ..... 12

3.0 Impact on Human and Animal Health ..... 12
3.1 Toxicology Summary (Appendix I, Table 3.1) ..... 12
3.2 Occupational/Bystander Exposure and Risk Assessment ..... 13
3.2.1 Occupational ..... 13
3.2.2 Bystander ..... 14
3.3 Dietary Exposure and Risk Assessment ..... 14
3.3.1 Food ..... 14
3.3.2 Drinking Water ..... 14
3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations ..... 14
3.4 Maximum Residue Limits ..... 15
3.5 Aggregate Exposure ..... 15

3.6 Cumulative Effects ..... 16

4.0 Impact on the Environment ..... 16
4.1 Fate and Behaviour in the Environment ..... 16
4.2 Effects on Non-Target Species (Appendix I, Table 4.2) ..... 17
4.2.1 Effects on Terrestrial Organisms ..... 17
4.2.2 Effects on Aquatic Organisms ..... 19

5.0 Value ..... 20
5.1 Effectiveness Against Pests ..... 20
5.1.1 Acceptable Efficacy Claims ..... 20
5.2 Phytotoxicity to Host Plants ..... 21
5.2.1 Acceptable Claims for Host Plants ..... 22
5.3 Impact on Succeeding Crops ..... 22
5.4 Economics ..... 22
5.5 Sustainability ..... 22
5.5.1 Survey of Alternatives ..... 22
5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management ..... 23
5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance ..... 23
5.5.4 Contribution to Risk Reduction and Sustainability ..... 24

6.0 Toxic Substances Management Policy Considerations ..... 24

7.0 Summary ..... 25
7.1 Methods for Analysis of the Microorganism as Manufactured ..... 25
7.2 Human Health and Safety ..... 25
7.3 Environmental Risk ..... 26
7.4 Value ..... 27

8.0 Regulatory Decision ..... 28

List of Abbreviations ..... 31

Appendix I ..... 33
Table 3.1 Acute Toxicity and Infectivity of *Sclerotinia minor* strain IMI 344141 and Its Associated End-use Products Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide ..... 33
Table 4.2 Toxicity to Non-Target Species ..... 35

List of References ..... 39

# OVERVIEW

## Registration Decision for *Sclerotinia minor* strain IMI 344141

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*[1] and in accordance with the Pest Control Products Regulations, has granted conditional registration for the sale and use of Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide containing *Sclerotinia minor* strain IMI 344141 to suppress dandelion top growth in turf.

Current scientific data from the applicant and relevant scientific reports were evaluated to determine if, under the proposed conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

This report summarizes the information evaluated and provides the results of the evaluation as well as the reasons for the conditional registration, with an outline of the additional scientific information required from the applicant. It also describes the conditions of registration that applicants must meet to ensure that the health and environmental risks as well as the value of these pest control products are acceptable for their intended use.

This overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on human health, environmental and value assessment of Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide containing *Sclerotinia minor* strain IMI 344141.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks[2] to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration. The Act also requires that products have value[3] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 As per subsection 28(1) of the *Pest Control Products Act*.

2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

3 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g., children) as well as organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

## What Is *Sclerotinia minor* strain IMI 344141?

*Sclerotinia minor* strain IMI 344141 is a living fungus and is the active ingredient in Sarritor Technical Herbicide and its associated end-use products Sarritor Granular Biological Herbicide (Commercial) for commercial use and Sarritor Domestic Biological Herbicide for domestic use. The fungus infects susceptible dandelion plants and destroys dandelion plant tissues above ground (top growth). The end-use products can be applied broadcast with a drop spreader onto the surface of turf infested with actively growing dandelions or by spot application directly to individual dandelion plants. The main component of the herbicide effect on the dandelion plants appears to be oxalic acid, which is secreted by *Sclerotinia minor*.

## ❖ Health Considerations

### ♦ Can Approved Uses of *Sclerotinia minor* strain IMI 344141 Affect Human Health?

***Sclerotinia minor* strain IMI 344141 is unlikely to affect your health when used according to the label directions of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Biological Granular Herbicide.**

People could be exposed to *Sclerotinia minor* strain IMI 344141 when handling the end-use products or when these are being applied. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only the uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to *Sclerotinia minor* strain IMI 344141 and identify the dose where no effects are observed.

*Sclerotinia minor* strain IMI 344141 caused significant health effects in laboratory animals when a large dose was applied to the respiratory tract. As a result, the precautionary wording "DO NOT breathe dust" is required on the product labels. Furthermore, commercial as well as domestic applicators are required to wear respiratory protection suitable for preventing inhalation of biological products.

- **Residues in Water and Food**

**Dietary risks from food and water are not of concern.**

*Sclerotinia minor* is common in nature and is found around the world where the climate is temperate. Application of *Sclerotinia minor* strain IMI 344141 to turf is not expected to significantly increase the natural environmental background levels of *Sclerotinia minor*. No adverse effects from dietary exposure have been attributed to natural populations of *Sclerotinia minor* and none were observed during acute oral toxicity testing. Furthermore, no food uses are proposed for *Sclerotinia minor* strain IMI 344141. The establishment of a maximum residue limit (MRL) is therefore not required for *Sclerotinia minor* strain IMI 344141 under Section 4(d) of the *Food and Drugs Act* as defined under Division 15, Section B.15.002 of the Food and Drug Regulations.

- **Occupational Risks From Handling Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide**

**Occupational risks are not of concern when Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide are used according to the label directions, which include protective measures.**

Commercial and domestic applicators handling or applying Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide can come into direct contact with *Sclerotinia minor* strain IMI 344141 on the skin, in the eyes or by inhalation. Although Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide are not irritating to the skin or eyes, they contain substances that have the potential to cause hypersensitive reactions following repeated exposure. For this reason, the label requires that a long-sleeved shirt, long pants, shoes, socks and waterproof gloves be worn during handling and application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide. As the inhalation of dust from Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide has the potential to cause adverse effects in the lungs, respiratory protection is required during handling and application of these products to turf.

For the general population, skin exposure could occur during maintenance or recreational activities on treated turf, but is not expected to pose an undue risk on the basis of the low toxicity profile for *Sclerotinia minor* strain IMI 344141 by the oral and dermal routes of exposure. Once the product is applied to turf under the appropriate environmental conditions, airborne dust is not expected to be a concern, based on the granular formulation. Label directions indicate that Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide should be applied when rainfall or irrigation will occur within 12 hours of application. This way, the potential that the bystanders inhale dust containing *Sclerotinia minor* strain IMI 344141 is expected to be reduced when the applied product is wet. Health risk to bystanders is therefore not of concern.

Although no adverse effects were reported in workers using *Sclerotinia minor* strain IMI 344141, Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide during product development, like all microbes, *Sclerotinia minor* strain IMI 344141 contains substances that can cause hypersensitivity. As a result, commercial and domestic applicators are required to wear a long-sleeved shirt, long pants, shoes, socks and waterproof gloves during application to prevent repeated skin exposure. The label statement "POTENTIAL SENSITIZER" and the precautionary wording "May cause sensitization" are required on the product labels.

## ❖ Environmental Considerations

### ♦ What Happens When *Sclerotinia minor* strain IMI 344141 Is Introduced Into the Environment?

***Sclerotinia minor* strain IMI 344141 is pathogenic to terrestrial and aquatic plants; therefore, label statements will instruct applicators to avoid direct application to non-target plants, ornamental ponds, aquatic, estuarine or marine habitats.**

*Sclerotinia minor* is widespread in the environment, and there are no published reports of disease associated with *Sclerotinia minor* in birds, wild mammals, earthworms, honeybees and other arthropods, aquatic invertebrates or fish. A laboratory study showed that *Sclerotinia minor* strain IMI 344141 is not toxic or pathogenic to birds when ingested. *Sclerotinia minor* is a food source for many ground-dwelling arthropods, indicating that it is of low toxicity to terrestrial arthropods. *Sclerotinia minor* strain IMI 344141 did not affect earthworms at concentrations expected in the environment following a single application at the highest product label rate. *Sclerotinia minor* causes disease in many species of terrestrial plants. The product label statements instruct users to avoid applying Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to plants growing adjacent to treated turf. Aquatic arthropods and fish were exposed to a range of test aquatic concentrations. Laboratory studies indicate that aquatic plants are the most sensitive aquatic organisms tested. The measures established to minimize risk to sensitive aquatic plants will be sufficient to protect fish and aquatic arthropods. Label statements instruct applicators not to apply Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to ornamental ponds or aquatic, estuarine or marine habitats and not to allow mower clippings to enter such habitats for a few weeks after application. Sarritor Granular Biological Herbicide (Commercial), Sarritor Domestic Granular Herbicide granules and *Sclerotinia minor* strain IMI 344141 do not persist in the environment and are not readily transferred from the site of application to aquatic habitats.

## ❖ Value Considerations

♦ **What Is the Value of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide?**

**Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide contain a living fungus that infects dandelion plants and suppresses dandelion top growth in turf.**

Application of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide effectively suppresses dandelion top growth in turf. Based on the mode of action of *Sclerotinia minor* strain IMI1344141, the development of herbicide resistance is unlikely. The availability of *Sclerotinia minor* strain IMI1344141 would enable further development of integrated and sustainable turf management practices, especially where the use of traditional chemical herbicides is not desirable.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

**Key Risk-Reduction Measures for Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide**

- **Human Health**

To minimize the potential for the development of hypersensitivity to *Sclerotinia minor* strain IMI 344141 in commercial and domestic applicators, users are required to wear a long-sleeved shirt, long pants, shoes, socks and waterproof gloves to minimize skin exposure to *Sclerotinia minor* strain IMI 344141.

Laboratory studies indicate the inhalation of large quantities of *Sclerotinia minor* strain IMI 344141 has the potential to cause inflammation of the lungs. As a result, users are required to wear a dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any –95, R-95, P-95 or HE filter for biological products when handling, mixing/loading or applying the product and during all clean-up/repair activities.

To ensure that domestic users have ready access to the appropriate protective equipment, the applicant is required to provide a suitable respirator with each package of Sarritor Domestic Granular Biological Herbicide.

- **Environment**

Because *Sclerotinia minor* strain IMI 344141 is harmful to terrestrial and aquatic plants, a warning statement is included on the labels to avoid dosing of non-target plants, ornamental ponds or aquatic, estuarine or marine habitats. Users are instructed to direct mower clippings away from such habitats for the first few weeks after Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide application.

## What Additional Scientific Information Is Required?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, as a condition of these registrations, the applicant must submit additional scientific information to ensure that *Sclerotinia minor* strain IMI 344141 will not harm terrestrial arthropods (honeybees) or non-arthropod invertebrates (earthworms). More details are presented in the Science Evaluation section of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information within the time frames indicated.

- **Environment**

    - A replacement study to confirm that honeybees will not be harmed while foraging on treated dandelion flowers. Submission of the replacement study to the PMRA must be made no later than 1 May 2008.

    - A replacement study to confirm that earthworms will not be harmed following an application of these products. Submission of the replacement study to the PMRA must be made no later than 1 May 2008.

## Other Information

As these conditional registrations relate to a decision on which the public must be consulted[4], the PMRA will publish a consultation document when there is a proposed decision on the applications to convert the conditional registrations to full registrations or on the applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e., the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

---

[4] As per subsection 28(1) of the *Pest Control Products Act*.

# SCIENCE EVALUATION

## 1.0 The Active Ingredient, Its Properties and Uses

### 1.1 Identity of the Active Ingredient

| | |
|---|---|
| Active microorganism | *Sclerotinia minor* strain IMI 344141 |
| Function | To suppress dandelion top growth in turf. |
| Binomial name | *Sclerotinia minor* strain IMI 344141 |
| Taxonomic designation | |
| Kingdom | Fungi (Mycetae) |
| Phylum | Ascomycota |
| Class | Discomycetes (Leotiomycetes) |
| Order | Heliotiales |
| Family | Sclerotiniaceae |
| Genus | *Sclerotinia* |
| Species | *Sclerotinia minor* Jagger (Jagger 1920) |
| Strain | IMI 344141 |
| Patent status information | Canadian Patent No. 2,292,233, Watson *et al.* was granted 24 May 2005 |
| Nominal purity of active | 300 CFU/g |
| Identity of relevant impurities of toxicological and/or environmental significance | The technical grade active ingredient does not contain any impurities or microcontaminants known to be TSMP Track-1 substances. The product meets microbiological contaminants release standards and no mammalian toxins are known to be produced by *Sclerotinia minor* strain IMI 344141. |

## 1.2 Physical and Chemical Properties of the Active Substances and End-use Products

**Technical Product - Sarritor Technical Herbicide**

| Property | Result |
|---|---|
| Colour and physical state | n/a |
| Odour | n/a |
| Formulation type | n/a |
| Guarantee | n/a |
| Container material and description | n/a |
| Density | n/a |
| pH of 1% dispersion in water | n/a |
| Oxidizing or reducing action | n/a |
| Storage stability | n/a |
| Explodability | n/a |

n/a - not applicable for Sarritor Technical Herbicide. Sarritor Technical Herbicide is an integrated product.

**End-use Products - Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide**

| Property | Result |
|---|---|
| Colour | Beige |
| Odour | Odourless to faintly sour |
| Physical state | Granules |
| Formulation type | Live Organism (LO) |
| Guarantee | 300 CFU/g |
| Container material and description | 25 kg plastic bag (Commercial product)<br>15 kg plastic bag (Domestic product) |
| Density | 1.03 g/mL |
| pH | 4.7 |
| Oxidizing or reducing action | n/a |

| Property | Result |
|---|---|
| Storage stability | 7 months if stored refrigerated<br>9 months if stored frozen |
| Explodability | n/a |

n/a = not applicable

### 1.3 Directions for Use

Sarritor Granular Biological Herbicide (Commercial) is used for the suppression of dandelion top growth in commercial lawns, golf courses, municipal parks, and turf farms. Sarritor Domestic Granular Biological Herbicide is used for the suppression of dandelion top growth in domestic lawns. Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide can be applied broadcast with a drop spreader onto the surface of turf infested with actively growing dandelion at a rate of 40 or 60 g product/$m^2$ (12 000 or 18 000 Colony Forming Units (CFUs)/$m^2$). For spot application, Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide can be directly applied to individual dandelion plants at a rate of 0.2 or 0.4 g product/plant (60 or 120 CFUs/plant).

Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide can be applied at a rate of 40 g product/$m^2$ in the spring and/or the fall when daytime high temperatures are 18-24°C and rainfall or irrigation will occur within 12 hours of application. The higher application rate of 60 g product/$m^2$ can be applied when environmental conditions are suboptimal (i.e., daily maximum temperatures are outside of the optimal range of 18-24°C, but do not surpass 27°C) and/or when the turf is highly infested with dandelions. Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide should not be applied in hot and dry weather.

Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide cannot be mixed with any chemical pesticides.

### 1.4 Mode of Action

Oxalic acid, secreted by *Sclerotinia minor*, appears to be the main component of its phytotoxicity to dandelion plants. The mechanisms by which oxalate secretions contribute to *Sclerotinia minor* virulence centre on three modes of action: (1) several of the fungal enzymes secreted during invasion of plant tissues have maximal activities at low pH, thus oxalate may aid *Sclerotinia minor* virulence by shifting the apoplastic pH to a value better suited for enzymatic degradation of plant cell walls; 2) oxalate may be directly toxic to host plants, presumably because of its acidity, thereby facilitating invasion; and 3) chelation of cell wall $Ca^{2+}$ by the oxalate anion compromises the function of $Ca^{2+}$ dependent defence responses thus weakening the plant cell wall.

The action of *Sclerotinia minor* strain IMI 344141 on dandelion plants is very rapid with symptoms appearing within 3 to 5 days following application. The level of dandelion top growth suppression quickly reaches a plateau and then begins to decline 4 weeks after treatment.

## 2.0 Methods of Analysis

### 2.1 Methods for Identification of the Microorganism

Methods to uniquely identify the Microbial Pest Control Agent (MPCA) are a key component of manufacturing quality assurance. The genus *Sclerotinia* is characterized by a sclerotial stroma that develops free from host tissues and does not incorporate host tissues into the medulla (Kohn 1979). The species *Sclerotinia minor* is characterized by irregularly shaped sclerotia (0.5–2.0 mm in diameter) with a black outer rind and white inner cortex, borne superficially. In culture, sclerotia form abundantly throughout the colony, sometimes adhering to form an aggregate crust. The sclerotial medulla is formed of tightly woven hyaline texture oblita. Cells are 5–10 µm wide, with heavily gelatinized walls 2–3 µm thick. The sclerotial rind consists of 2–6 layers of texture prismatica, originating from medullary cells bending perpendicular to the surface, becoming brown-walled, and inflated (5–15 µm in diameter).

Strain IMI 344141 is differentiated from other strains by mycelial incompatibility testing and sclerotial morphology. The MPCA is compatible with strains LRC 2104, ATCC44236, Sm44 and Sm66 (Vegetative Compatibility Group 1). Sclerotia of strain IMI 344141 are significantly longer and wider on oatmeal agar, and wider on potato dextrose agar compared with other Group 1 strains (1.72 ± 0.35 mm in length and 1.63 ± 0.51 mm in width on potato dextrose agar, and 1.69 ± 0.51 mm in length and 1.53 ± 0.40 mm in width on oatmeal agar). Strain IMI 344141 is most easily differentiated from other isolates by sclerotial production (number). On potato dextrose agar, fewer than 100 sclerotia are produced per plate (92.3 ± 2.08 sclerotia/plate) compared with other isolates (215–741 sclerotia/plate).

### 2.2 Methods for Establishment of Purity of Seed Stock

A *Sclerotinia minor* strain IMI 344141 master stock is maintained frozen in liquid nitrogen. To renew the master stock, the contents of a frozen vial are plated on potato dextrose agar (PDA). The plate is examined to confirm that the stock is viable and that there is no visible evidence of contamination. Agar plugs from the growing edges of the PDA starter plates are suspended in 10% glycerol and stored in liquid nitrogen. After one week of storage in liquid nitrogen, the contents of one vial are plated on potato dextrose agar to confirm viability. When only two vials of the parent culture remain in the liquid nitrogen storage tank, the strain is restocked as described above using one of the remaining vials as the starting culture.

A working stock is prepared by inoculating PDA plates with the master stock. Agar plugs are cut from the plates, and suspended in sterile distilled water in a screw-cap tube. These agar plugs are stored at 4°C until needed to inoculate primary flasks.

## 2.3 Methods to Define the Content of the Microorganism in the Manufactured Material Used for the Production of Formulated Products

The potency and purity of the product is routinely checked throughout the manufacturing process by plating on PDA. During formulation of the end-use product, the microbial pest control agent becomes integrated into the product granules, making it difficult to enumerate. To address this difficulty 25 granules are plated onto PDA and the number of granules yielding fungal colonies is divided by the total number to give the percent of viable granules. The product guarantee, 300 CFU/g, refers to the of number granules per gram of product, rather than the number of mycelial cells. The potency of each batch is confirmed by measuring the area of necrosis on a detached dandelion leaf 24 or 48 hours after a single granule is applied to a drop of sterile water on the leaf surface. An area of necrosis greater than 3–4 mm is considered to be acceptable.

## 2.4 Methods to Determine and Quantify Residues (Viable or Non-viable) of the Active Microorganism and Relevant Metabolites

*Sclerotinia minor* is ubiquitous in nature, and globally widespread in temperate zones. Application of *Sclerotinia minor* strain IMI 344141 is not expected to significantly increase the natural environmental background levels of this microorganism. No adverse effects from dietary exposure have been attributed to natural populations of *Sclerotinia minor* and none were observed during acute oral toxicity testing. Furthermore, no food uses are proposed for *Sclerotinia minor* strain IMI 344141. The establishment of a maximum residue limit (MRL) is therefore not required for *Sclerotinia minor* strain IMI 344141 under Section 4(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division 15, Section B.15.002 of the Food and Drugs Regulations.

## 2.5 Methods for Determination of Relevant Impurities in the Manufactured Material

Microbial contamination during the manufacture of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide is minimized by the use of aseptic culture methods and clean-room practices. The purity of the culture is confirmed throughout the process by plating on tryptic soy agar and examining plates for signs of contamination after incubation at 34°C. The batch is discarded if contamination is detected.

## 2.6 Methods to Show Absence of Any Human and Mammalian Pathogens

Certificates of analysis were submitted for screening of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide for potential contaminant microorganisms, including aerobic sporeformers, fecal streptococcus, coliforms, fecal coliforms, yeasts, moulds, *Shigella*, *Salmonella*, *Vibrio cholerae*, *Vibrio parahaemolyticus* and *Staphylococcus aureus* using acceptable standard analytical methods. These organisms were not detected in any of the five tested batches. Monitoring for microbiological contaminants is routinely conducted as part of the quality assurance program.

### 2.7 Methods to Determine Storage Stability, Shelf-Life of the Microorganism

As loss of viability was expected in the products during storage, the applicant defined an acceptable loss of viability by correlating field efficacy with laboratory-defined viability (mean colony diameter on potato dextrose agar). There was no significant decrease in field potency in plots inoculated with sub-batches found in laboratory testing to have a 30% loss of viability. A 30% loss of viability on storage was therefore considered to be acceptable.

Different storage conditions and packaging methods were tested to determine the shelf life of the products. Water activity and temperature had the greatest effect on viability. Storage at -16°C for up to 9 months, at 4°C for up to 7 months and up to 20°C for up to 3 months was considered acceptable.

## 3.0 Impact on Human and Animal Health

### 3.1 Toxicology Summary (Appendix I, Table 3.1)

The PMRA conducted a detailed review of the toxicological database for *Sclerotinia minor* strain IMI 344141. The database was largely complete, consisting of laboratory animal (in vivo) toxicity studies (acute oral toxicity, acute pulmonary toxicity) and one infectivity (intraperitoneal injection) study using the MPCA as the test substance. A dermal toxicity study, including scoring of dermal irritation and an eye irritation study using the end-use products as the test substance were also included in the database. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to characterize the toxicity and infectivity of these pest control products.

*Sclerotinia minor* strain IMI 344141 is of low acute toxicity by the oral route in CD (Sprague Dawley) rats. Adverse effects observed in rats dosed with *Sclerotinia minor* strain IMI 344141 by intratracheal instillation (pneumonia) and intraperitoneal injection (peritonitis) did not appear to be due to an infective process, but were likely due to the immune response to large quantities of microbial antigen injected into the trachea, or into a normally-sterile body cavity, the peritoneum. Label statements requiring personal protective equipment and judicious handling to minimize inhalation exposure of commercial or domestic applicators are required. Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide were non-toxic by the dermal route and non-irritating to minimally irritating when applied to the skin and eyes of New Zealand White rabbits.

Although no incidents of hypersensitivity were reported during the development and testing of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide, all microbial pest control agents are considered to contain substances that are potential sensitizers. Label statements indicating that Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide are potential sensitizers and label precautions requiring personal protective equipment and judicious handling to minimize exposure in commercial workers or domestic applicators are required.

Higher tier subchronic and chronic toxicity studies were not required because there were no indications of infectivity or pathogenicity in the test animals treated in the Tier I acute oral and pulmonary toxicity/infectivity tests. Using the product as directed and following the precautionary measures presented on the product labels will effectively mitigate the risks.

Within the available scientific literature, there are no reports that suggest that *Sclerotinia minor* strain IMI 344141 has the potential to cause adverse effects in the endocrine system of animals. In the submitted intraperitoneal toxicity and infectivity study in rodents, the immune system is intact and sequestration of the test substance is proceeding.

There was no evidence in the available scientific literature to indicate that *Sclerotinia minor* strain IMI 344141 is capable of producing mammalian genotoxins or other toxins.

### 3.2 Occupational/Bystander Exposure and Risk Assessment

#### 3.2.1 Occupational

When handled according to the label directions, the pulmonary, dermal and ocular routes are potential routes of applicator exposure to *Sclerotinia minor* strain IMI 344141.

Oral exposure is not expected to occur and based on results of acute oral toxicity studies in laboratory animals, incidental oral exposure is not expected to be a health concern.

Dermal exposure is expected during application of the end-use products and from contact with treated turf during maintenance and recreational activities. Based on results of dermal toxicity and dermal irritation studies in laboratory animals, dermal exposure is not expected to pose a risk to human health. Because all microbial pesticides are considered to be potential sensitizers, long sleeved shirt, long pants, shoes, socks and waterproof gloves must be worn by applicators to prevent repeated dermal exposure to microbial substances in Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide.

Inhalation exposure is expected to be limited due to the granular formulation of the end-use products and the application method. Nevertheless, in consideration of the toxic effects noted in an intratracheal instillation study, the precautionary label statement "DO NOT breathe dust" and personal protective equipment (dust/mist filtering respirator (MSH/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any –95, R-95, P-95 or HE filter for biological products) are required to mitigate the risk of inhalation exposure during application of the products.

To ensure domestic applicators have ready access to the appropriate protective equipment, the registrant is required to provide a suitable respirator with each package of Sarritor Domestic Granular Biological Herbicide. If the registrant alters the product packaging of Sarritor Domestic Granular Biological Herbicide from the current large bag format to a dispenser that minimizes the dust produced during application and limits use to spot application only, domestic applicators will not be required to wear respiratory protection.

### 3.2.2 Bystander

Once Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is applied to turf under the appropriate environmental conditions, airborne dust is not expected to be a concern, based on the granular formulation. Label directions indicate that Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide should be applied when rain or irrigation will occur within 12 hours of application. This wetting of the applied product is expected to further reduce the potential for the inhalation of dust containing *Sclerotinia minor* strain IMI 344141 by bystanders. Other bystander exposures are not expected to pose an undue risk on the basis of the low toxicity profile for *Sclerotinia minor* strain IMI 344141 by the oral and dermal routes of exposure.

## 3.3 Dietary Exposure and Risk Assessment

### 3.3.1 Food

As *Sclerotinia minor* strain IMI 344141 is to be applied to turf and not to food, the proposed use pattern is not expected to result in dietary exposure. Incidental oral exposure is expected to pose negligible to no risk for the general population, including infants and children or animals, because *Sclerotinia minor* strain IMI 344141 demonstrated no toxicity by the oral route and no infectivity. Dietary exposure to secondary metabolites produced by *Sclerotinia minor* strain IMI 344141 is also not expected and the organism is not known to produce metabolites of concern to human or animal health. Based on the results of acute oral toxicity studies, there is no concern for chronic risks posed by dietary exposure of the general population and sensitive subpopulations, including infants and children.

### 3.3.2 Drinking Water

Sarritor Granular Biological Herbicide (Commercial), Sarritor Domestic Granular Biological Herbicide granules and *Sclerotinia minor* strain IMI 344141 are not readily displaced from the site of application and the product labels prohibit application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide near aquatic ecosystems, so contamination of drinking water is considered unlikely. Furthermore, *Sclerotinia minor* strain IMI 344141is susceptible to municipal treatment of drinking water. Oral exposure via contamination of drinking water is therefore not expected.

### 3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Calculation of acute reference doses (ARDs) and acceptable daily intakes (ADIs) is not usually possible for predicting acute and long term effects of microbial agents in the general population or to potentially sensitive subpopulations, particularly infants and children. The single (maximum hazard) dose approach for testing MPCAs is sufficient for conducting a reasonable general assessment of risk if no significant adverse effects (i.e., no acute toxicity, infectivity or pathogenicity endpoints of concern) are noted in acute toxicity and infectivity tests. Based on all the available information and hazard data, the PMRA concludes that *Sclerotinia minor* strain IMI 344141 is of low toxicity by the oral route, is not pathogenic or infective to mammals and

that infants and children are likely to be no more sensitive to the MPCA than the general population. Thus there are no threshold effects of concern and as a result, no need to require definitive (multiple dose) testing or to apply uncertainty factors to account for intra- and interspecies variability, safety factors or margins of exposure. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of the MPCA, including neurological effects from pre- or post-natal exposures and cumulative effects on infants and children of the MPCA and other registered microorganisms that have a common mechanism of toxicity, do not apply to this MPCA. As a result, the PMRA has not used a margin of exposure (safety) approach to assess the risks of *Sclerotinia minor* strain IMI 344141 to human health.

### 3.4 Maximum Residue Limits

*Sclerotinia minor* is ubiquitous in nature and globally widespread in temperate zones. Application of *Sclerotinia minor* strain IMI 344141 is not expected to significantly increase the natural environmental background levels of this microorganism. No adverse effects from dietary exposure have been attributed to natural populations of *Sclerotinia minor* and none were observed during acute oral toxicity testing. Furthermore, no food uses are proposed for *Sclerotinia minor* strain IMI 344141. The establishment of a maximum residue limit (MRL) is therefore not required for *Sclerotinia minor* strain IMI 344141 under Section 4(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division 15, Section B.15.002 of the Food and Drugs Regulations.

### 3.5 Aggregate Exposure

Based on the submitted toxicity and infectivity test data and other relevant information in the PMRA's files, there is reasonable certainty that no harm will result to the Canadian population, including infants and children, from aggregate exposure to residues of *Sclerotinia minor* strain IMI 344141, when the microbial pest control product is used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information. Oral exposure is not expected to occur and based on results of acute oral toxicity studies in laboratory animals, incidental oral exposure is not expected to be a health concern. Dermal exposure is expected to occur during application of the end-use products and from contact with treated turf during maintenance and recreational activities. Based on results of dermal toxicity and dermal irritation studies in laboratory animals, dermal exposure is not expected to pose a risk to human health. As all microbial pesticides are considered to be potential sensitizers, the use of protective clothing and waterproof gloves by applicators are required to prevent repeated exposure of the skin to microbial substances in Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide. Inhalation exposure following application is expected to be limited due to the granular formulation of the end-use products. Nevertheless, considering the effects noted in the intratracheal instillation study, personal protective equipment is required to mitigate the risk of inhalation exposure during application of the end-use products. The label

directions indicate that the product should be applied when a rainfall or irrigation occurs within 12 hours of application. This wetting of the applied end-use products is expected to reduce the potential for the inhalation of dust containing *Sclerotinia minor* strain IMI 344141 by bystanders.

### 3.6 Cumulative Effects

The PMRA has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. The toxic effects noted on intratracheal instillation and intraperitoneal injection of *Sclerotinia minor* strain IMI 344141 are thought to be due to the response of the immune system to large quantities of microbial antigen. Given that the immune response is largely antigen-specific, these effects are not expected to be cumulative. Other than naturally occurring strains of *Sclerotinia minor*, the PMRA is not aware of any other microorganisms or other substances that share a common mechanism of toxicity with this active ingredient. No cumulative effects are anticipated if the residues of *Sclerotinia minor* strain IMI 344141 interact with related strains of this microbial species.

## 4.0 Impact on the Environment

### 4.1 Fate and Behaviour in the Environment

A request to waive the data requirement for environmental fate and behaviour testing of *Sclerotinia minor* strain IMI 344141 was submitted. Environmental fate data (Tier II/III) were required due to some toxicological effects in non-target organisms identified in Tier I testing. Environmental fate testing is intended to demonstrate whether an MPCA is capable of surviving or replicating in the environment to which it is applied and could provide an indication of which non-target organisms may be exposed to the MPCA as well as provide an indication of the extent of exposure. The submitted waiver request provided information from the published literature and results from laboratory and field testing of Sarritor Granular Biological Herbicide (Commercial), Sarritor Domestic Granular Biological Herbicide and *Sclerotinia minor* strain IMI 344141.

Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granules are not readily dislodged from the site of application. When applied, the granules settle through the turf and rest on the soil surface. Eruptive mycelial growth of *Sclerotinia minor* strain IMI 344141 from Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules does not persist in the absence of a host and quickly decays. Field experiments, using lettuce as a highly susceptible indicator species, showed no residual infectivity in the turf environment 4 months after the application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules to dandelion plants. Formation of sclerotia following application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to turf is rare and occurs mainly in the fall, more commonly associated with clumps of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide

granules than with infected weed tissue. Although sclerotia represent the most resistant, resting stage of the fungus, they also have a limited survival in the field. In field soil box experiments, the viability of sclerotia decreased rapidly in soil and after 11 months, no sclerotia could be recovered. In laboratory and field compost experiments, sclerotia were rapidly inactivated in active compost. The dissemination of *Sclerotinia minor* strain IMI 344141 from the site of application is minimal, with the exception that mowing may spread diseased dandelion clippings onto susceptible plants growing adjacent to treated turf and these may develop lesions or disease. The possibility that vectors could disseminate *Sclerotinia minor* strain IMI 344141 from the site of application was also investigated. The MPCA could not be recovered from the seeds of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide treated dandelion plants, suggesting that seeds will not provide a vector for the off-target transfer of *Sclerotinia minor* strain IMI 344141. Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules could also be spread following ingestion by granivorous animals. Although some sclerotia could be recovered from the feces of cattle and mallard ducks, sclerotial viability was greatly reduced and fungal mycelia growing on Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules are expected to be even more susceptible to the environment of the digestive tract. Dispersal of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules by scatter-hoarding animals (e.g., chipmunks, squirrels) remains a possibility, but is expected to be of minimal risk to non-target plants.

Overall, the off-target spread of *Sclerotinia minor* strain IMI 344141 from sites treated with Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is expected to be minimal and *Sclerotinia minor* strain IMI 344141 is not expected to persist in the environment.

## 4.2 Effects on Non-Target Species (Appendix I, Table 4.2)

### 4.2.1 Effects on Terrestrial Organisms

Evaluation of the risk of *Sclerotinia minor* strain IMI 344141 to terrestrial organisms was based on toxicity data submitted for birds, honeybees and earthworms. Requests to waive the requirement for testing in wild mammals, other terrestrial arthropods and terrestrial plants were also submitted and considered as part of the risk assessment.

*Sclerotinia minor* strain IMI 344141 did not cause mortality, clinical signs or findings of necropsy within 30 days in 14-day-old Northern Bobwhite (*Colinus virginianus*) dosed daily for five consecutive days by oral gavage with a mycelial suspension of *Sclerotinia minor* strain IMI 344141 ($1.7 \times 10^7$ CFU/kg body weight/day). Infectivity was not assessed, as the viability of the MPCA in the test substance was not verified and there was no attempt made to recover the MPCA from the tissues or organs. Based on the maximum growth temperature of *Sclerotinia minor* strain IMI 344141 (34°C) and on results of an intraperitoneal injection study in laboratory rats, infectivity is not expected in homeothermic animals. The requirement for wild mammal testing was waived based on the lack of infectivity reported in laboratory mammals tested as part of *Human Health and Safety Testing*, in which no toxic effects were noted in an acute oral toxicity study and Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic

Granular Biological Herbicide were shown to be of low dermal toxicity and to be non- to minimally irritating to the skin and eyes. Effects, including pneumonia and death, were identified during pulmonary testing of laboratory mammals. These were thought to be due to an overwhelming immune response to the large quantities of microbial antigen introduced into the lungs by intratracheal instillation. Wild mammals are unlikely to be exposed to quantities sufficient to elicit such a response.

*Sclerotinia minor* is not known as a pathogen of terrestrial invertebrates. Organisms that feed on or parasitize fungal sclerotia include nematodes, earthworms, centipedes, snails, gall midge larvae (Diptera: Cecidomyiidae), mites (Astigmata: Acaridae), bacteria and fungi (Coley-Smith and Cooke 1971). Larvae of the fungus gnat (*Bradysia* species) and larvae of spring tails (*Onychirus* species: Collembola) were observed feeding on sclerotia of *Sclerotinia sclerotiorum* (Anas and Reeleder 1987, 1988). The low incidence of lettuce drop in Quebec muck soils is partially attributed to the feeding of *Bradysia* species larvae on sclerotia, in addition to the activities of mycoparasite moulds *Trichoderma*, *Sporidesmium*, *Gliocladium* and *Penicillium*. In a review of the published literature, no incidents of toxicity or pathogenicity were identified. Given that the distribution of *Sclerotinia minor* is widespread, reports in the literature would be expected if it were a pathogen of terrestrial invertebrates. Nevertheless, equivocal results in laboratory testing of honeybees and earthworms require replacement studies.

In a dietary toxicity study in honeybees (*Apis mellifera*), mortality was greater in groups fed a diet containing live or killed *Sclerotinia minor* strain IMI 344141 compared with negative controls. The study authors attributed this to reduced palatability of the adulterated diet, but because feed consumption was not measured, this could not be confirmed and a toxic effect could not be ruled out. The 8-day dietary $LC_{50}$ and NOEC were not calculated, but mortality in the test group fed a diet containing 100 CFU/mL in the diet was 48% and mortality in honeybees fed a diet containing 1 CFU/mL was greater than in the negative control group. As honeybees are likely to forage for nectar on treated flowering dandelion plants, a replacement study is required to convincingly demonstrate that these effects are not toxic or pathogenic in nature.

Although no clinical or behavioural effects were noted in earthworms exposed to environmental concentrations equivalent to those expected immediately following a single application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide at the highest label rate, the concentration range tested did not meet the requirement for maximum hazard testing. No range-finding study was done to justify the low concentrations tested. Due to the certain exposure of earthworms to Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide, a replacement study is required in which earthworms are exposed to the maximum hazard concentration of 267 g of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide/kg dry soil.

A waiver request of the requirement for toxicity/pathogenicity data for *Sclerotinia minor* strain IMI 344141 on non-target terrestrial plants was submitted. The waiver request is based on the rationale that the active ingredient is a known plant pathogen with a wide host range (Melzer *et al.* 1997, Hollowell and Shew 2001, Pacific Northwest Fungi Data Base 2005). Testing is therefore not considered necessary to assess the risks of Sarritor Granular Biological Herbicide

(Commercial) or Sarritor Domestic Granular Biological Herbicide to terrestrial plant species. Experimental testing for phytotoxicity on broadleaf garden weeds, turf grasses and representative garden plants was conducted. Many broadleaf garden weeds were susceptible to infection with *Sclerotinia minor* strain IMI 344141 following spot treatment with Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules. Turf grasses (Kentucky bluegrass, creeping red fescue, perennial ryegrass, annual ryegrass, creeping bentgrass, colonial bentgrass, chewing fescue, tall fescue and hard fescue) were resistant to infection by *Sclerotinia minor* strain IMI 344141 following both pre- and post-emergent applications of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide. The risk to non-target plants will be limited to those growing in or adjacent to treated turf as Sarritor Granular Biological Herbicide (Commercial), Sarritor Domestic Granular Biological Herbicide granules and *Sclerotinia minor* strain IMI 344141 do not persist in the environment and are not readily dispersed from the site of application. The Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide product labels advise users to avoid application to desirable broadleaf species.

### 4.2.2 Effects on Aquatic Organisms

The risk of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide to aquatic organisms was based on evaluation of toxicity data in one fish, one aquatic arthropod, and one aquatic plant species.

A 30-day toxicity study of 50 rainbow trout (*Oncorhynchus mykiss*) and a 21-day study in *Daphnia magna* were considered to be supplementary information because the range of aquatic concentrations tested (20, 39, 79, 158 and 315 CFU/mL) was insufficient to properly assess the risk of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to aquatic organisms. Maximum hazard testing is recommended where the toxicity of the test substance is expected to be low. This requires a concentration of 1000 times the expected environmental concentration or $10^6$ CFU/mL, whichever is greater and achievable. Although the formulation of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granules makes it difficult to define the estimated environmental concentration in terms of a mycelial suspension, the dose used is clearly insufficient to meet the requirement for maximum hazard testing. An $LC_{50}$ could not be calculated from the data and no range-finding test was submitted to justify the use of a lower dose. Although a single fish in the highest test group died, there was no evidence that this was a treatment-related mortality, as there were no associated clinical signs or findings on necropsy. No effects were observed in *Daphnia magna*. In spite of the insufficiency of the submitted studies, no replacement studies are required. In another study (see below), Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide were shown to be pathogenic to an aquatic vascular plant, which was the most sensitive aquatic organism tested. Measures to mitigate the risk to aquatic vascular plants will therefore be sufficient to mitigate any potential risk to freshwater fish or invertebrates.

Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granules effects on the freshwater floating aquatic vascular plant *Lemna gibba* G3 was

studied at concentrations of 4, 9, 20, 45 and 100 granules/100 mL under static conditions. A negative (no granules), blank (uninoculated granules) and heat-inactivated control treatments were also observed. The 7-day EC50 based on frond number was 44 granules/100 mL, with a 95% confidence interval of 0.0–88.0 granules/100 mL. The 7-day no observed effect concentration based on biomass was 9 granules/100 mL. As adverse effects in *Lemna* were not observed in the heat-inactivated control and because fungal mycelia were observed on the fronds in the 100 granules/100 mL treatment group, the effects observed in the treatment groups are thought to be due to infection of the plant tissues with *Sclerotinia minor* strain IMI 344141.

A waiver of the requirement for further aquatic plant toxicity/pathogenicity testing for *Sclerotinia minor* strain IMI 344141 was requested, based on the known host range of *Sclerotinia minor* which includes aquatic sedges, on results of the 7-day toxicity test with duckweed (*Lemna gibba* G3) and on the ability of *Sclerotinia minor* strain IMI 344141 mycelia to germinate from floating Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granules and for mycelial threads to grow along the surface of the water. Adverse effects in emergent and floating aquatic plants are therefore expected if Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules are permitted to enter aquatic ecosystems. To mitigate against the risk of effects in aquatic plants, the end-use product labels specifically prohibit application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to aquatic, estuarine or marine ecosystems and applicators are instructed not to apply Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to self-contained ponds such as garden ornamental ponds to prevent nuisance damage to ornamental aquatic plants. In addition, the end-use label indicates to direct mower clippings away from such habitats for the first few weeks after Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide application.

## 5.0 Value

### 5.1 Effectiveness Against Pests

Data from a total of 34 efficacy trials conducted over 6 years in Ontario, Quebec and Nova Scotia were submitted. Although the submitted trials were unique in terms of the experimental design and field layout from year to year, an appropriate experimental design was used and an appropriate set of treatments was included in each trial to address the proposed pest claim.

The efficacy of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide for suppression of dandelion top growth in turf was visually assessed as percent weed control and compared to an untreated weedy check and a chemical herbicide, Killex (containing the active ingredients dicamba, 2,4-D and mecoprop). Observations were made at various times throughout the growing season.

#### 5.1.1 Acceptable Efficacy Claims

Adequate data indicated that a rate of 40 g product/$m^2$ of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is required for suppression of

dandelion top growth in turf where conditions are optimal, i.e., where daily high temperature ranges from 18 to 24°C, the relative humidity is high and/or where rainfall or irrigation occurs within 12 hours following the application. Mean dandelion top growth suppression following the application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide at 40 g product/$m^2$ was 79.0% over 7 trials at the first rating (7 Days After Treatment (DAT)), 82.8% over 8 trials at the second rating (11-15 DAT), 82.1% over 8 trials at the third rating (21-28 DAT) and 79.3% over 5 trials at the last rating (42-45 DAT).

As Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide contain a living fungus, the level of dandelion top growth suppression may vary with environmental factors that influence fungal germination, growth and development. Data from 6 trials indicated that a rate of 60 g product/$m^2$ is required for an acceptable level of dandelion top growth suppression in turf where conditions are suboptimal, i.e., where daily high temperatures are outside of the range of 18-24°C. Mean dandelion top growth suppression following the application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide at 60 g product/$m^2$ in these trials was 77.5% at the first rating (7 DAT), 77.0% at the second rating (11-15 DAT), 85.0% at the third rating (21-28 DAT) and 75.2% at the last rating (42-45 DAT).

The biological activity of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide is very rapid with symptoms appearing within 3 to 5 days after application. Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide provided 80 - 90% density reduction of the established dandelion immediately after treatment when the environmental conditions are optimal. A few weeks after treatment, the fungus population density decreases below the effective threshold. Consequently, the suppression of dandelion top growth with Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide declined and dandelion regrowth was found later in the season. The use of proper turf management practices, i.e., fertilizer, irrigation, etc. are essential in the prevention of re-growth of the treated dandelion plants.

### 5.2 Phytotoxicity to Host Plants

Data from a total 26 trials, 24 field trials and 2 dedicated crop tolerance trials (greenhouse trials), conducted over 5 years in Ontario, Quebec and Nova Scotia were submitted. Although the submitted trials were unique in terms of the experimental design and field layout from year to year, an appropriate experimental design was used and an appropriate set of treatments was included in each trial to address the proposed host claim.

Crop tolerance was visually assessed as percent injury for a total of 9 turfgrass species: Kentucky bluegrass, annual ryegrass, perennial ryegrass, creeping bentgrass, colonial bentgrass, tall fescue, Chewing's fescue, creeping red fescue and hard fescue during the growing season. These species are representative of the grass species planted in turf in Canada.

### 5.2.1 Acceptable Claims for Host Plants

Dicotyledonous plant species are sensitive to *Sclerotinia minor*. Only three monocotyledonous plant species, asparagus, tulips and banana are known to be susceptible. *Sclerotinia minor* is not a serious pathogen on most plants as economic losses to *Sclerotinia minor* have only been reported in lettuce and peanuts. *Sclerotinia minor* is not pathogenic on any grass species, but is pathogenic to many weeds associated with turf and grass crops. *Sclerotinia minor* Jagger isolate (IMI 344141) was obtained from a lettuce field in Sherrington, Quebec in 1983 and is endemic to Ecoregions 1, 3, and 4 (coastal BC, Alberta, southern Ontario, Quebec and the Maritimes). In the US, *Sclerotinia minor* has been reported in Arizona, California, Connecticut, Florida, Illinois, Minnesota, Montana, New York, North Carolina, Oklahoma, Oregon, Pennsylvania, Texas, Virginia and Washington.

Data demonstrated acceptable safety of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide to the tested turfgrass species under both greenhouse (favourable to disease infection and development) and field environmental conditions. Crop injury data with Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide support a crop tolerance claim for turfgrasses.

## 5.3 Impact on Succeeding Crops

Not applicable.

## 5.4 Economics

Not available.

## 5.5 Sustainability

### 5.5.1 Survey of Alternatives

Manual removal of dandelion plants, although time-consuming, is feasible on a small individual property. Heavy infestations in this situation could be controlled initially with chemical herbicides such as 2,4-D based products alone or in a tank mixture (Table 5.5.1-1) and managed thereafter with a manual removal program. Periodic applications of herbicides may be required if infestations become unmanageable.

In large turf areas such as parks, athletic fields, golf courses etc., it is not feasible to manually remove dandelion plants and chemical dandelion control has been the common practice. It should be noted that specific municipalities have limited the use or banned the use of chemical herbicides.

**Table 5.5.1-1 Herbicides Options for Dandelion Control in Turf**

| Technical Grade Active Ingredient | End-use Products | Herbicide Classification | |
|---|---|---|---|
| | | Group | Mode of Action |
| 2,4-D | 2,4-D | 4 | Synthetic auxin |
| MCPA | Compitox | 4 | Synthetic auxin |
| 2,4-D + mecoprop + dicamba | Killex | 4 | Synthetic auxin |
| Metsulfuron methyl | Escort | 2 | ALS inhibitor |

The availability of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide provides both homeowners and commercial applicators with another option for dandelion top growth suppression in situations where the use of synthetic chemicals is not desirable.

### 5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide offer an alternative to the use of chemical herbicides for dandelion top growth suppression in turf. The availability of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide enables further development of integrated and sustainable turf management practices, especially in areas where chemical herbicides are undesirable.

The application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is compatible with the integrated pest management practices in turf. The suppression of dandelion top growth with Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide promotes a strong and healthy lawn that is better able to compete with invasive weeds. The use of proper turf management practices, i.e., fertilizer, irrigation, etc. are essential in the prevention of re-growth of the treated dandelion plants.

### 5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Based on the mode of action of *Sclerotinia minor* strain IMI 344141, the development of resistance is unlikely. Development of resistance of dandelion to Group 4 Herbicides, such as 2,4-D, has not been an issue in Canada but the availability of alternate products like Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological

Herbicide provides an option to reduce the possibility of such an occurrence. The use of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide in conjunction with synthetic chemical herbicides may minimize the potential for dandelion resistance to *Sclerotinia minor* strain IMI 344141.

### 5.5.4 Contribution to Risk Reduction and Sustainability

The use of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide offers an alternative to traditional Group 4 chemical herbicides in turf. As such, Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide may contribute to a reduction in the use of chemical herbicides in turf.

It is also expected that the use of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide may improve the integrated pest management practices in turf, especially in areas where the use of traditional chemical herbicides is undesirable.

## 6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's *Toxic Substances Management Policy*, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

While reviewing *Sclerotinia minor* strain IMI 344141, the PMRA took into account the federal Toxic Substances Management Policy and followed its Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with its use were also considered, including microcontaminants in the technical product and formulants in the end-use products Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide. The PMRA has reached the following conclusions:

- *Sclerotinia minor* strain IMI 344141 does not meet the Track 1 criteria because the active ingredient is a biological organism and hence is not subject to the criteria used to define persistence, bioaccumulation and toxicity properties of chemical control products. There are also no formulants, contaminants or impurities present in the end-use products that would meet the TSMP Track-1 criteria.

- Sarritor Technical Herbicide does not contain any contaminants of health or environmental concern identified in Canada Gazette Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

- The end-use products Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide do not contain any formulants of health or environmental concern identified in Canada Gazette Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

Therefore, the use of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide is not expected to result in the entry of Track 1 substances into the environment.

## 7.0 Summary

### 7.1 Methods for Analysis of the Microorganism as Manufactured

The product characterization data for the microbial active ingredient, *Sclerotinia minor* strain IMI 344141 and its associated end-use products Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide are considered adequate to assess their potential risks to human health and the environment. The technical and end-use materials were fully characterized and the specifications were supported by the analysis of a sufficient number of batches. Microbe-specific screening data on representative production batches showed an absence of potential contaminants of concern, including aerobic sporeformers, fecal streptococcus, coliforms, fecal coliforms, yeasts, moulds, *Shigella*, *Salmonella*, *Vibrio cholerae*, *Vibrio parahaemolyticus* and *Staphylococcus aureus*. No additional testing is required to demonstrate that the manufacturer's quality assurance program is successful at limiting contaminating microorganisms.

Storage stability data were sufficient to support different expiration dates on the product labels for Sarritor Technical Herbicide, Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide. Storage temperature was shown to have the greatest impact on the microorganism's viability. The product labels stipulate the duration of storage based on temperature, allowing for storage up to 9 months at –16°C, up to 7 months at 4°C and up to 3 months at 20°C.

### 7.2 Human Health and Safety

The acute toxicity and infectivity studies submitted in support of *Sclerotinia minor* strain IMI 344141 were determined to be sufficiently complete to permit a decision on registration. *Sclerotinia minor* strain IMI 344141 was of low toxicity in the rat when administered via the oral and dermal routes. Significant effects were observed when the MPCA was administered via intratracheal injection (pneumonia) and intraperitoneal injection (peritonitis) in the rat, likely caused by a natural immune response to large quantities of microbial antigen rather than by infection. The Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide granular formulation was shown to be non-irritating to minimally irritating when applied to the skin and eyes of the rabbit.

Although there have been no hypersensitivity reactions reported in people during the development and testing of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide, all microbial pest control agents are considered to be potential sensitizers. Exposure to allergens, including *Sclerotinia minor* strain IMI 344141 may cause allergic reactions following repeated exposures to high concentrations. As a result, the signal words "POTENTIAL SENSITIZER" are required on the principal display panels of all product labels.

When handled according to the label instructions, the pulmonary, dermal and ocular routes are the potential routes of exposure to applicators. To minimize risk to applicators, use of appropriate personal protective equipment (PPE) is stipulated on the Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide product labels, including the wearing of long sleeved shirt, long pants, shoes plus socks and waterproof gloves. Given the particular risk from inhalation exposure to *Sclerotinia minor* strain IMI 344141, applicators of both the commercial and domestic end-use products are required to wear an appropriate biological dust/mist filtering respirator. To further minimize bystander exposure to airborne dust particles, label directions indicate that the product should be applied when a rainfall or irrigation will occur within 12 hours of application.

As no food uses are proposed for Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide, the establishment of a maximum residue limit (MRL) is therefore not required for *Sclerotinia minor* strain IMI344141 under Section 4(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division 15, Section B.15.002 of the Food and Drugs Regulations. Any incidental exposure to food crops is expected to pose negligible to no risk to the general population, including infants and children or animals because *Sclerotinia minor* strain IMI 344141 was not toxic or infective via the oral route of administration. The potential exposure from contaminated drinking water is also negligible given that the product label prohibits application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide near aquatic habitats and that *Sclerotinia minor* strain IMI 344141 is likely susceptible to municipal treatment of drinking water.

### 7.3 Environmental Risk

Data and information submitted on the environmental fate and effects of *Sclerotinia minor* strain IMI 344141 were determined to be sufficiently complete to assess the environmental impact of this microbial pest control agent.

Information on the environmental fate and behaviour of *Sclerotinia minor* strain IMI 344141 was required because toxicological concerns were identified in certain non-target organism studies. Laboratory and field testing of Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide revealed that granules were not readily dislodged from the site of application on turf after settling through the turf and resting on the soil surface. Eruptive mycelia growth of *Sclerotinia minor* strain IMI 344141 from Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide granules were also shown to not persist in the absence of a plant host and as a result quickly disappear.

Field experiments showed little residual herbicidal activity in turf four months after application to dandelion plants. Moreover, the potential for seasonal carryover of residues was also unlikely with this MPCA, as it rarely forms sclerotia, which are more resistant to harsh environmental conditions than mycelia, and when formed by strain IMI 341441, quickly lose their viability.

*Sclerotinia minor* is widespread in the environment, yet there are no published reports of disease associated with *Sclerotinia minor* in birds, wild mammals, earthworms, honeybees and other arthropods, aquatic invertebrates or fish. A laboratory study showed that *Sclerotinia minor* strain IMI 344141 is not toxic or pathogenic to birds when ingested. Results from a laboratory study in honeybees were difficult to interpret, but *Sclerotinia minor* is a food source for many other ground-dwelling arthropods, indicating that this microorganism is of low toxicity to terrestrial arthropods. Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide did not affect earthworms at concentrations expected in the environment following a single application at the highest label rate, but higher concentrations were not tested. *Sclerotinia minor* causes disease in many species of terrestrial plants. The product labels instruct users to avoid applying Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to plants growing adjacent to treated turf.

Aquatic arthropods and fish were exposed to a range of test aquatic concentrations, however, the PMRA requirement for a maximal concentration of 1000 times the expected environmental concentration was not provided. As this maximum concentration was not tested it is not possible to properly assess the risk of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to these organisms. However, laboratory studies indicate that aquatic plants are the most sensitive aquatic organism tested as they were susceptible to *Sclerotinia minor* disease at concentrations lower than the maximal concentration of 1000 times the expected environmental concentration. Therefore, the measures established to minimize risk to sensitive aquatic plants will be sufficient to protect fish and aquatic arthropods.

Label statements instruct applicators not to apply Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide to ornamental ponds or aquatic, estuarine or marine habitats or to allow mower clippings to enter such habitats for a few weeks after application. Sarritor Granular Biological Herbicide (Commercial), Sarritor Domestic Granular Biological Herbicide granules and *Sclerotinia minor* strain IMI 344141 do not persist in the environment and are not readily transferred from the site of application to aquatic habitats, so these precautions are considered sufficient to minimize the risk to aquatic organisms. Additional test data and/or information are required to further refine the impact assessment of strain IMI 344141 on pollinators (honeybee) and earthworms.

### 7.4 Value

The data submitted to register Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide are sufficient to support the claim for suppression of dandelion top growth in turf. Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide offer an alternative to the use of chemical herbicides for

top growth suppression of dandelion in turf, especially where the use of traditional chemical herbicides is not desirable.

## 8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, has granted conditional registration for the sale and use of Sarritor Technical Herbicide containing *Sclerotinia minor* IMI 344141 and the end-use products Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide to suppress dandelion top growth in turf.

An evaluation of current scientific data from the registrant and scientific reports has resulted in the determination that, under the approved conditions of use, the end-use products have value and do not present an unacceptable risk to human health or the environment.

Although the risks and value have been determined to be acceptable when all risk reduction measures are followed, as a condition of these registrations, additional scientific information is being requested from the applicant as a result of this evaluation to ensure that *Sclerotinia minor* strain IMI 344141 will not harm terrestrial arthropods (honeybees) or non-arthropod invertebrates (earthworms). (For more details, refer to the Section 12 Notice associated with these conditional registrations.) The applicant will be required to submit this information within the time frames indicated below.

**NOTE:** The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

- **Environment**

Two studies are required:

- Observations in honeybees were difficult to interpret. Mortalities in honeybees fed a diet containing *Sclerotinia minor* strain IMI 344141 were higher than in controls. The study authors suggested that the diet containing *Sclerotinia minor* strain IMI 344141was unpalatable to the honeybees, and that the higher mortalities observed were due to food avoidance, rather than toxicity or pathogenicity. This could have been confirmed if the rate of food consumption was measured in test and control honeybees and it was shown that test honeybees ate less food. As food consumption was not measured, a toxic or pathogenic effect could not be ruled out. A replacement study is required to confirm that honeybees will not be harmed while foraging on treated dandelion flowers. Submission of the replacement study to the PMRA must be made no later than May 1, 2008.

- The range of test concentrations used in the submitted earthworm study was too low. The study showed that Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide were safe for earthworms exposed to

concentrations of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Biological Herbicide expected in soil immediately following a single application at the highest label use rate, but toxicity testing requires the use of a maximum hazard concentration one thousand times as high. A sound scientific rationale supporting the waiver of this requirement is required. Alternatively, a replacement study may be submitted with testing at the maximum hazard concentration (267 g/kg dry soil). Submission of the waiver rationale or study to the PMRA must be made no later than May 1, 2008.

## List of Abbreviations

| | |
|---|---|
| ADI | acceptable daily intake |
| ARD | acute reference dose |
| bw | body weight |
| CFU | colony forming unit |
| DAT | days after treatment |
| EC50 | effective concentration on 50% of the population |
| EP | end-use product |
| FDA | Food and Drugs Act |
| g | gram |
| kg | kilogram |
| $LC_{50}$ | lethal concentration 50% |
| MAS | maximum average score |
| MIS | maximum irritation score |
| mg | milligram |
| mL | millilitre |
| MPCA | microbial pest control agent |
| MRL | maximum residue limit |
| NOEC | no observed effect concentration |
| PCPA | *Pest Control Products Act* |
| PDA | potato dextrose agar |
| PMRA | pest management regulatory agency |
| ppm | parts per million |
| TSMP | toxic substances management policy |
| µm | micro-metre |

# Appendix I

**Table 3.1 Acute Toxicity and Infectivity of *Sclerotinia minor* strain IMI 344141 and Its Associated End-use Products Sarritor Granular Biological Herbicide (Commercial) and Sarritor Domestic Granular Biological Herbicide**

| Study Type | Species | Result | Comment | Reference |
|---|---|---|---|---|
| **Acute Toxicity/Infectivity** | | | | |
| Acute Oral Toxicity | Rat–Sprague-Dawley<br><br>5/sex treated with MPCA, limit dose $5.4 \times 10^7$ CFU/kg bw | LD50 > $5.4 \times 10^7$ CFU/kg bw | No clinical signs indicative of toxicity or pathogenicity, no mortalities.<br><br>The requirement for infectivity testing was waived based on the results of the intraperitoneal infectivity study.<br><br>NOT TOXIC | PMRA 1287822 |
| Acute Pulmonary Toxicity | Rat–Sprague-Dawley<br><br>5/sex treated with live or killed MPCA, limit dose $3 \times 10^4$ CFU/animal | LD50 not calculated | Mortalities in 2/10 animals treated with live, and 2/10 animals treated with killed test substance, accompanied by clinical signs including lethargy and dyspnea. Evidence of pneumonia was observed at necropsy. No clinical signs were observed in surviving animals.<br><br>The requirement for infectivity testing was waived based on the results of the intraperitoneal infectivity study and on the similarity of effects seen in rats treated with live and killed MPCA.<br><br>PRECAUTIONARY LABELLING REQUIRED | PMRA 1287823 |

| Study Type | Species | Result | Comment | Reference |
|---|---|---|---|---|
| Intraperitoneal Infectivity | Rat–Sprague-Dawley<br><br>12 males and 11 females treated with live MPCA, limit dose $\geq 2.7 \times 10^7$ CFU/animal, 7/sex treated with killed MPCA concentration equivalent to limit dose | LD50 not calculated | Mortalities in 4/7 males and 6/7 females treated with killed test substance and 6/12 males and 4/11 females treated with live test substance. Clinical signs observed in most treated animals included lethargy, piloerection, hunchback, dyspnea, diarrhea, weight loss, abdominal distension and abdominal lump. Necropsy findings were suggestive of acute peritonitis with eventual sequestration of the test substance.<br><br>The MPCA could not be recovered from tissue and organs of rats treated with live test substance by a validated method. Based on this, and the similarity of effects seen in animals treated with live and killed MPCA, infectivity is not suspected.<br><br>NOT INFECTIVE | PMRA 1287824 |
| Acute Dermal Toxicity | Rabbit–New Zealand Albino<br><br>2g/kg bw EP | LD50 > 2000 mg/kg bw | No clinical signs indicative of toxicity, no mortalities.<br><br>NOT TOXIC | PMRA 1287825 |
| Dermal Irritation | Rabbit–New Zealand Albino<br><br>2 g/kg bw EP (24 hour occluded exposure) | MIS[a] 1.4/8 at 24 hours<br><br>MAS[b] 0.667/8 | NON-IRRITATING TO MILDLY IRRITATING | PMRA 1287826 |
| Primary Eye Irritation | Rabbit–New Zealand Albino<br><br>100 mg EP | MIS 2/110 at 1 and 24 hours<br><br>MAS 0.667/110 | NON-IRRITATING TO MINIMALLY IRRITATING | PMRA 1287829 |

[a] MAS = Maximum irritation score.
[b] MAS = Maximum average score for 24, 28 and 72 hours

## Table 4.2 Toxicity to Non-Target Species

| Organism | Study Type | Species | Test Substance | Toxicity Data | Reference |
|---|---|---|---|---|---|
| **Terrestrial Organisms** | | | | | |
| **Vertebrates** | | | | | |
| Birds | Oral | Bobwhite quail | *Sclerotinia minor* strain IMI 344141 mycelial suspension<br><br>30 birds given a single dose of $1.7 \times 10^7$ CFU/kg bw daily for 5 consecutive days | LD50 > $1.7 \times 10^7$ CFU/kg bw/day × 5 days<br><br>NOEC > $1.7 \times 10^7$ CFU/kg bw/day × 5 days<br><br>No mortalities, no clinical signs, no findings on necropsy<br><br>NOT TOXIC | PMRA 1291623 |
| Mammals | Acute | No study was submitted. In a waiver request, a literature search showed no reports of adverse effects in wild mammals despite the ubiquitous nature of the MPCA. The waiver request also cited laboratory animal studies reviewed as part of the Human Health and Safety database. Exposure of wild mammals is expected to be minimal, with ingestion of the EP granules by granivorous mammals the most probable route of exposure, accompanied by dermal exposure from handling the granular product. Laboratory animal studies showed that *Sclerotinia minor* strain IMI 344141 is not infective in rats, and is non-toxic by the oral route in rats, and non-toxic and non-irritating by the dermal route in rabbits.<br><br>WAIVER ACCEPTED | | | PMRA 1291624 |
| **Invertebrates** | | | | | |
| Bee | Dietary | *Apis mellifera* | *Sclerotinia minor* strain IMI 344141 mycelial suspension<br><br>25 bee/group, dosed at 100, 10 or 1 CFU/mL diet | Study terminated on Day 8 when mortalities in controls exceeded 20%.<br><br>7 day cumulative mortalities in all test groups were ≥40%, and in the group fed a diet containing 100 CFU/mL, 7-day cumulative mortality was 48%. Study authors proposed that mortalities were due to reduced palatability of diet, but rates of food consumption were not measured, so this could not be confirmed.<br><br>LC50 and NOEC not statistically defined.<br><br>SUPPLEMENTARY | PMRA 1291626 |

| Organism | Study Type | Species | Test Substance | Toxicity Data | Reference |
|---|---|---|---|---|---|
| Other arthropods | Acute | No study was submitted. In a waiver request, a literature search showed no reports of adverse effects in arthropods, and that several arthropod species, representing multiple arthropod classes and orders are known to actively feed on *Sclerotinia minor* sclerotia, including centipedes (Class: Chilopoda), gall midge larvae (Order Diptera), mites (Order Astigmata), fungus gnat larvae (Order Diptera) and springtail larvae (Order Collembola).<br><br>WAIVER ACCEPTED | | | PMRA 1291627 |
| Earthworm | Acute | *Eisenia fetida* | Sarritor granules<br><br>10 worms/ group dosed at 6.25, 125, 250, 500 or 1000 mg/kg dry soil | LC50 > 1000 mg/kg dry soil<br>NOEC 1000 mg/kg soil<br><br>No mortalities, no clinical signs, and no aversion to treated soil observed at the highest tested concentration. Test concentrations did not meet the maximum hazard concentration of 267 g/kg soil (1000 times the estimated environmental concentration).<br><br>All worms (including untreated controls) lost weight because worms were not fed during the test. Worms fed heat-inactivated Sarritor lost significantly less weight than untreated control worms, possibly because the attenuated EP provided a food source.<br><br>SUPPLEMENTARY | PMRA 1291629 |
| Soil microbes | | No study or waiver request submitted. Test data are not required for *Sclerotinia minor* strain IMI 344141, as there are no reports of adverse effects in the available scientific literature. | | | |
| **Plants** | | | | | |
| Vascular Plants | Acute | No formal study was submitted. A waiver was requested based on the known host range of *Sclerotinia minor* including over 100 plant species, mostly dicots. Based on the requirement for direct contact with fungal mycelia, plants with a prostrate or rosette growth habit are the most likely to be affected by off-target application of Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Herbicide. An informal experimental report was To address the potential for pathogenicity in turf grasses, informal laboratory experimental reports were submitted. No adverse effects on any of the multiple turfgrass species tested were observed.<br><br>WAIVER ACCEPTED | | | PMRA 1291630 |

| Organism | Study Type | Species | Test Substance | Toxicity Data | Reference |
|---|---|---|---|---|---|
| **Aquatic Organisms** | | | | | |
| **Vertebrates** | | | | | |
| Freshwater fish | Acute | Rainbow trout | *Sclerotinia minor* strain IMI 344141<br><br>10 fish/group exposed to 20, 39, 79, 158 and 315 CFU/mL in the aquatic environment and 2, 4, 8, 16 and 32 CFU/kg in the diet. | There was one mortality in the group of fish exposed to 315 CFU/mL in the aquatic environment and 32 CFU/kg in the diet, but it was not evident that this death was treatment related, as no clinical signs or pathological findings on necropsy.<br><br>The test concentration was significantly below the maximum hazard concentration, and the viability of the mycelial suspension in the aquatic environment was not adequately confirmed.<br><br>SUPPLEMENTARY | PMRA 1291630 |
| Estuarine/ marine fish | Acute | No study or waiver request was submitted. Estuarine and marine fish are not expected to be exposed to the MPCA. | | | |
| **Invertebrates** | | | | | |
| Freshwater arthropods | Acute | *Daphnia magna* | *Sclerotinia minor* strain IMI 344141<br><br>20 neonate daphnids per group exposed to 20, 39, 79, 158, or 315 CFU/mL in the aquatic environment. | 21-day LC50 >315 CFU/mL<br>21-day NOEC 315 CFU/mL<br><br>No statistically significant differences in survival, reproduction or growth between treated daphnids and negative controls.<br><br>The test concentration was significantly below the maximum hazard concentration, and the viability of the mycelial suspension in the aquatic environment was not adequately confirmed.<br><br>SUPPLEMENTARY | PMRA 1291628 |
| Estuarine/ marine arthropods | Acute | No study or waiver request was submitted. Estuarine and marine arthropods are not expected to be exposed to the MPCA. | | | |
| Non-arthropod invertebrates | Acute | No study or waiver request was submitted. | | | |

| Organism | Study Type | Species | Test Substance | Toxicity Data | Reference |
|---|---|---|---|---|---|
| **Plants** | | | | | |
| Algae | Acute | No study or waiver request submitted | | | |
| Freshwater Plants | Acute | *Lemna gibba* | Sarritor granules<br><br>4, 9, 20, 45 granules/100 mL | 7-day frond no. EC50 44 granules/100mL ( 95% CI: 0-88 granules/100mL)<br><br>7-day frond no. growth rate EC50 63 granules/100mL (95% CI: 44-77 granules/100 mL)<br><br>7-day biomass EC50 58 granules/100mL (95% CI: 0-88 granules/100 mL)<br><br>7-day biomass growth rate EC50 71 granules/100mL (95% CI: 61–81 granules/100 mL)<br><br>NOEC = 9 granules/100 mL | PMRA 1291631 |
| Freshwater Plants | Acute | A request was submitted to waive the requirement for additional testing of aquatic plant species. Based on the known host range of *Sclerotinia minor* and results of the 7-day toxicity test with *Lemna gibba*, we can predict that floating broadleaf aquatic vegetation and sedges (Cyperaceae) are susceptible to infection if Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Herbicide granules enter the aquatic environment. Floating Sarritor Granular Biological Herbicide (Commercial) or Sarritor Domestic Granular Herbicide granules are capable of myceliogenic germination at the surface of the water, but are viable for fewer than 4 days. | | | PMRA 1291632 |

# List of References

## A. List of Studies/Information Submitted by Registrant

### 1.0 The Active Ingredient, Its Properties and Uses

### 2.0 Methods of Analysis


PMRA 1094852 Product Identification; Manufacturing Plant; Formulating Plant; Trade Name; Binomial Name; Canadian Patent Status. DACO M2.1, M2.2, M2.3, M2.4, M2.5, M2.6.

PMRA 1094846 Analytical Methodology: Active Ingredient or MPCA. Standard Operating Procedures for Detection of *Sclerotinia minor* in Water. DACO M2.1.0.1.

PMRA 1094845 Analytical Methodology: Active Ingredient or MPCA. Standard Operating Procedures for Media Preparation; Semi-selective media for *Sclerotinia minor*. DACO M2.10.1.

PMRA 1094847 Analysis for Microbial Contaminants. Comments: Cross-reference to M2.8 Manufacturing Methods. DACO M2.10.2

PMRA 1094848 Analysis for Other Unintentional Ingredients. DACO M2.10.3

PMRA 1094849 Storage Stability Testing; Storage of *Sclerotinia minor* (IMI344141) Barley-Based Formulation. DACO M2.11

PMRA 1094850 Summary of Physical and Chemical Properties. DACO M.2.12.

PMRA 1094851 Published References (82) Cited in M2, M2.12. DACO M. 2.14.

Abawi, G.S, and R.G. Grogan. 1979. Epidemiology of diseases caused by *Sclerotinia* species. Phytopath. 69(8): 899-904.

Abd-Elrazik, A.A., and J.W. Lorbeer. 1980. Rapid separation of *Sclerotinia minor* sclerotia from artificially and naturally infested organic soil. Phytopath. 70(9): 892-893.

Abu-dieyeh, M.H., J. Bernier and A.K. Watson. 2005. *Sclerotinia minor* triggers fruiting and reduces germination in dandelion *(Tarmicum officinale).* Biocontrol Science & Technology. Accepted for publication March 21, 2005.

Abu-dieyeh and A.K. Watson. 2005. Effect of turfgrass mowing height on biocontrol of dandelion with *Sclerotinia minor*. Biocontrol Science & Technology. Accepted for publication August 1,2005, pp. 1-37.

Adams, P.B. and W.A. Ayres. 1979. Ecology of *Sclerotinia* species. Phytopath. 9(8): 896-899.

Adams, P.B. 1987. Effects of soil temperature, moisture, and depth on survival and activity of *Sclerotinia minor, Sclerotinia cepivorum,* and *Sclerotinia sclerotivorum.* Plant Dis.71(2): 170-174.

Adams, P.B. 1989. Comparison of antagonists of *Sclerotinia* species. Phytopath. 79(12): 1345-1347.

Adandonon, A., T.A.S. Aveling, N.A. van der Menve and G. Sanders. 2005. Genetic variation among *Sclerotium* isolates from Benin and South Africa, determined using mycelial compatibility and ITS rDNA sequence data. Austral. Plant Path. 34: 19-25.

Afek, U., N. Aharoni and S. Carmeli. 1995. The involvement of marmesin in celery resistance to pathogens during storage and the effect of temperature on its concentration. Am. Phytopath. Soc. 85(9):1033-1036.

Afek, Ü., J Orenstein and N. Aharoni. 2002. The involvement of marmesin and its interaction with *GA3* and psoralens in parsley decay resistance. Can. J. Plant Pathol.24:61-64.

Alexander, B.J.R. and A. Stewart. 1994. Survival of sclerotia of *Sclerotinia* and *Sclerotium* spp in New Zealand horticultural soil. Soil Biol. Biochem. 26(10): 1323-1329.

Almeida, A.M.R., R.V. Abdelnoor, E. S. Calvo, D. Tessman and J.T. Yorinori. 2001. *Sclerotium* spp in New Zealand horticultural soil. Soil Biol. Biochem. 26(10): 1323-1329.

Genotypic diversity among Brazilian isolates of *Sclerotium rolfii.* J. Pytopath. 149:493-502.

Anas, O. and R.D. Reeleder. 1987. Recovery of fungi and arthropods from sclerotia of *Sclerotinia sclerotiorum* in Quebec muck soils. Phytopath. 77(2):327-330.

Anas, O. and R.D Reeleder. 1988. Consumption of sclerotia of *Sclerotinia sclerotiorum* by larvae of *Bradysia coprophila:* influence of soil factors and interactions between larvae and *Trichoderma viridk.* Soil Biol. Biochem. 20(5): 619-624.

APHIS-USDA. 2001. List of widely prevalent plant pathogenic fungi: by fungus: widely prevalent fungi list 2001.

Austed, J. and G. Kavli. 1983. Photoxic dermatitis caused by celery infected with *Sclerotinia sclerotiorum.* Contact Derm. 9:448-45 1.

Bardin, S.D. and H.C. Huang, 2001. Research on biology and control of *Sclerotinia* diseases in Canada. Can. J. Plant. Pathol. 23:88-98.

Beier, R.C. and E.H. Oertli. 1983. Psoralen and other liner furocoumarins as phytolexins in celery. Phytochem. 22(11): 2595-2597.

Beuchat, L.R. 1983. Influence of water activity on growth, metabolic activities and survival of yeasts and molds. J. Food Protect. 46(2): 135-141.

Bowen, C, H.A. Melouk, K.E. Jackson and M.E. Payton. 2000. Effect of a select group of seed protectant fungicides on growth of *Sclerotinia minor* in vitro and its recovery from infested peanut seed. Plant Dis. 84(11): 1217-1220.

Brière, S.C., Watson, A.K. and Hallett, S.G. 2000. Oxalic acid production and mycelial biomass yield of *Sclerotinia minor* or the formulation enhancement of a granular turf herbicide. Biocontrol Sc. & Tech. 10: 281-289.

Brosten, B.S. and D.C. Sands. 1986. Field trials of *Sclerotinia sclerotiorum* to control Canada thistle *(Cirsium arvense).* Weed Sci. 34:377-380.

Cessna, S.G., V.E. Sears, M.B. Dickman and P.S. Low. 2000. Oxalic acid, a pathogenicity factor for *Sclerotinia sclerotiorum,* suppresses the oxidative burst of the host plant. The Plant Cell 12:2191-2199.

Ciotola, M., L.A. Wymore and A.K. Watson. 1991. *Sclerotinia*, a potential mycoherbicide for lawns. Weed Abstracts, Weed Sc. Soc. Am. 31:81.

Coley-Smith, J.R. and R.C. Cooke. 1971. Survival and germination of fungal sclerotia. Annu. Rev. Phytopathol. 9:65-92.

de Jong, M.D., G.W. Bourdôt, G.A. Hurrell, D. J. Saville, H. J. Ebrink and J.C. Zadoks. 2002. Risk analysis for biological weed control-simulating dispersal of *Sclerotinia sclerotiorum* (Lib.) de Bary ascospores from a pasture after biological control of *Cirsium arvense* (L.) Scop. Aerobiologia. 18:211-222.

Dillard, H.R. and R.G. Grogan. 1985. Relationship between sclerotial spatial pattern and density of *Sclerotinia minor* and the incidence of lettuce drop. Phytopathol. 5(1): 90-93.

Durman, S.B., A.B. Menendez and A.M. Godeas. 2003. Mycelial compatability groups in Buenos Aires field populations of *Sclerotinia sclerotiorum* (Sclerotiniaceae). Austral, J. Bût. 51: 421-427.

Ekins, M.G., E.A.B. Aitkens and K.C. Goulter. 2002. Carpogenic germination of *Sclerotinia minor* and potential distribution in Australia. Austral. Plant Path. 31:259-265.

El-Tarabily, K.A., M.H. Soliman, A.H. Nassar, H.A. Al-Hassani, K. Sivasithamparam, F. McKenna and G.E. St. J. Hardy. 2000. Biological control of *Sclerotinia minor* using a chitinolytic bacterium and actinomycetes. Plant Path.49: 573-583.

Farr, D.F., G.F. Bills, G.P. Chamuris and A.Y. Rossman. Fungi on plants and plant products in the United States. Am. Phytopath. Soc. Sclerotium - 941.

Ginns, J.H. 1986. Compendium of plant disease and decay fungi in Canada 1960-1980. Biosystematics Res. Centre, Res.Branch, Agriculture Canada Pub. 18: 13.

Godoy, G., J.R. Steadman, M.B. Dickman and R. Dam. 1990. Use of mutants to demonstrate the role of oxalic acid in pathogenicity of *Sclerotinia sclerotiorum* on *Phaseolus vulgaris*. Physiol. & Mol. Plant Path. 37: 179-191.

Guimariies, R.L. and H.U. Stotz. 2004. Oxalate production by *Sclerotinia sclerotiorum* deregulates guard cells during infection. Plant Physiol. 136:3703-3711.

Hao, J.J., K.V. Subbarao and J.M. Duniway. 2003. Germination of *Sclerotinia minor* and *S. sclerotiorum* sclerotia under various soil moisture and temperature conditions. Pub.No.-2003- 0213-01R Am. Phytopath. Soc. 93(4):443-450.

Hao, J.J. and K.V. Subbarao. 2005. Comparitive analyses of lettuce drop epidemics caused by *Sclerotinia minor* and *S. sclerotiorum*. Plant Dis. 89(7):717-725.

Hawthorne, B.T. 1975. Observations on the development of apothecia of *Sclerotinia minor* Jagg. in the field. N.Z. J. Agric. Res. 19: 383-386.

Heath-Pagliuso, S., S.A. Matlin, N. Fang, R.H. Thompson and L. Rappaport. 1992. Stimulation of furanocoumarin accumulation in celery and celeriac tissues by *Fusarium oxysporum* F. SP. *PII*. Phytochem. 3l(8): 2683-2688.

Hind, T.L., G.J. Ash and G.M. Murray. 2001. *Sclerotinia minor* on canola petal in New South Wales-a possible airborne mode of infection by ascospores? Austral. Plant Path. 30: 289-290.

Hollowell, J.E., B.B. Shew, M.A. Cubeta and J.W. Wilcut. 2003. Weed species as hosts of *Sclerotinia minor* in peanut fields. Plant Dis. 87(2): 197-199.

Holst-Jensen, A., L.M. Kohn and T. Schumacher. 1997. Nuclear rDNA Phylogency of the Sclerotiniaceae. Mycologia, 89(6): 885-899.

Horsfall, J.G. and R.W. Barratt. 1945. An improved grading system for measuring plant diseases. [citation not reported]

Imolehin, E.D., R.G. Grogan and J.M. Duniway. 1980. Effect of temperature and moisture tension on growth, sclerotial production, germination, and infection by *Sclerotinia minor*. Phytopath. 70(12): 1153-1157.

Imolehin, E.D. and R.G. Grogan. 1980. Factors affecting survival of sclerotia, and effects of inoculum density, relative position, and distance of sclerotia from the host on infection of lettuce by *Sclerotinia minor*. Phytopath. 70(12): 1162-1 167.

Jagger, I.C. 1920. *Sclerotinia minor,* N. SP., the cause of a decay of lettuce, celery, and other crops. J. Agric. Res. XX (4):331.

Jarvis, W.R. 1985. *Sclerotinia minor* as the cause of lettuce drop in southwestern Ontario. Can. Plant Dis. Surv. 65:1.

Jones, E.E. and A. Stewart. 1997. Biological control of *Sclerotinia minor* in lettuce using *Trichoderma* species. NZ Plant Prot. Cod. 1997: 154-158.

Keay, M.A.1938. A study of certain species of the genus *Sclerotinia.* Ann. Appl. Biol.XXVI (2): 227-247.

Kemp, J.D., B.E. Langlois and J.D. Fox. 1981. Effects of vacuum packaging and potassium sorbate on yield, yeast and mold growth, and quality of dry-cured hams. J. Food Sci. 46:1015-1017, 1024.

Kohn, L.M. 1979. A monographic revision of the genus *Sclerotinia.* Mycotaxon IX. (2): 365-444.

Kohn, L.M., E. Stasovski, I. Carbone, J. Royer and J.B. Anderson. 1991. Mycelial incompatibility and molecular markers identify genetic variability in field populations of *Sclerotinia sclerotiorum.* Pytopath. 81(4): 480-485.

Kora, C. and G.J. Bowland. 2002. First report of foliar and root infection of carrot by *Sclerotinia minor* in Ontario, Canada. Plant Dis. 86:, No. 12

Li, S., A., Mao, Y. Shang and X. Liu. 2003. *Monacrosporium janus* sp. nov., a new nematode-trapping hyphomycete parasitizing sclerotia and hyphae of *Sclerotinia sclerotiorum*. Mycol. Res. 107(7): 888-894.

Livingstone, D.M., Hampton, J.L., P.M. Phipps and E.A. Grabau. 2005. Enhancing resistance to *Sclerotinia minor* in peanut by expressing barley oxalate oxidase gene. Plant Physiol. 137: 1354- 1362.

Lutzoni, F. *et al.* 2004. Assembling the funal tree of life: progress, classification, and evolution of subcellular traits. *Am.* J. of Bot. 91(10): 1446-1480.

Matheron, M.E. and M. Porchas.2005. Influence of soil temperature and moisture on eruptive germination and viability of sclerotia of *Sclerotinia minor* and *S. sclerotiorum*. Plant Dis. 89(1): 50-54.

Maxwell, D.P. and R.D. Lumsden. 1970. Oxalic acid production by *Sclerotinia sclerotiorum* in infected bean and in culture. Phytopath. 60: 1395-1398.

Melouk, H.A., L.L. Singleton, F.N. Owens and C.N. Akem. 1986. Survival of sclerotia of *Sclerotinia minor* in the digestive tract of a ruminant. Phytopath. 76(10): 1115.

Melouk, H.A., L.L. Singleton and D.G. Glasgow. 1990. Reduced viability of sclerotia of *Sclerotinia minor* after ingestion by mallard duck. Phytopath. 80(4): 1990.

Melzer, M.S., E.A. Smith and Boland, G.J. 1997. Index of plant hosts of *Sclerotinia minor*. Can. J. Plant Path. 19: 272-280.

Miller, R.V., Ford, E.J. and D.C. Sands. 1989. A nonsclerotial pathogenic mutant of *Sclerotinia sclerotiorum*. Can. J. Microbiol. 35: 517-520.

Mortensen, K. and E.J. Hogue. 1995. *Sclerotinia sclerotiorum* as a potential biological control agent for diffuse knapweed on dry rangeland in interior British Columbia. Proc. 8th Int. Symp. Biol. Cont. Weeds: 397-406.

Mugnier, J. and G. Jung. 1985. Survival of bacteria and fungi in relation to water activity and the solvent properties of water in biopolymer gels. Appl. Env. Microbiol. 50(1): 108-114.

Porter, D.M. and M.K. Beute. 1974. Sclerotinia blight of peanuts. Phytopath. 64: 263-264.

Riddle, G.E., L.L. Burpee and G.J. Boland. 1991. Virulence of *Sclerotinia sclerotiorum* and *S. minor* on dandelion *(Taraxucum officinale).* Weed Sci. 39: 109- 118.

Ridgway, H.J., N. Rabeendran, K. Eade and A. Stewart. 2001. Application timing of *Coniothyrium minitans* A69 influences biocontrol of *Sclerotinia minor* in lettuce. NZ Plant Protect. 54: 89-92.

Sandhu, S.S., R.C. Rajak and G.P. Agarwal. 1993. Studies on prolonged storage of *Beauveria bassiana* conidia: effects of temperature and relative humidity on conidial viability and virulence against chickpea borer, *Helicoverpa armigera.* Biocont. Sci. & Technol. 3: 47-53.

Sarma, B.K., U.P. Singh and K.P. Singh, 2002. Variability in Indian isolates of *Sclerotium rolfsii.* Mycologia. 94(6): 1051-1058.

Schell, L.D., V.B. Perone, R.L. Larkin and R.E. Kupel. 1963. The isolation and characterization of two phytotoxic fiiranocoumarins (psoralens) from diseased celery. Biochem. 2(5): 1127-1131.

Schnick, P.J. and G.J. Boland. 2002. 2,4-D and Sclerotinia minor to control common dandelion. Weed Sci. 50: 173-178.

Shabana, Y.M. , D. Muller-Stover and J. Sauerborn. 2003. Granular pest formulation of *Fusarium* oxysporum f sp. *orthoceras* for biological control of sunflower broomrape: efficacy and shelf-life. Biol. Cont. 26: 189-201.

Southwood, T.R.E. 2.2 The sampling programme. Ecological Methods, Chapman and Hall. p. 17-25.

Steadman, J.R., J. Marcinkowska and S. Rutledge. 1994. A semi-selective medium for isolation of *Sclerotinia sclerotiorum.* Can. J. Plant Path. 16: 68-70.

Stewart-Wade, S.M., S. Green, G.J. Boland, M.P. Teshler, I.B. Teshler, A.K. Watson, M.G. Sampson, K. Patterson, A. DiTommaso and S. Dupont. *Taraxacum officinale* (Weber), dandelion (Asteraceae). Chapter 82: 427-430

Subbarao, K.V. 1998. Progress toward integrated management of lettuce drop. Plant Dis. 82(10): 1068-1077.

Toms, H.N.W. 1964. Plant diseases of southern British Columbia a host index. Can. Plant Dis. Surv. 44(3): 143/180.

Tuite, J. Plant Pathological Methods: Fungi and bacteria. p.52-53.

Viji, G., W. Uddin, N.R. O'Neill, S. Mischke and J.A. Saunders. 2004. Genetic diversity of *Sclertoinia homoeocarpa* isolates from turfgrasses from the various regions of North America. Plant Dis. 88(11): 1269-1276.

Willetts, H.J. and J.S. Wong. 1980. The biology of *Sclerotinia sclerotiorum, S. trifoliorum,* and *S. minor* with emphasis on specific nomenclature. Bot. Rev. 46(2): 101-165.

Woodward, K.E. and C.E. Simpson. 1993. Characterization of growth and sclerotial production of *Sclerotinia minor* isolated from peanut in Texas. Plant Dis. 7(6): 576-579.

Wu, C.M., P.E. Koehler and J.C. Ayres. 1972. Isolation and identification of xanthotoxin (8-methoxypsoralen) and bergapten (5-methoxypsoralen) from celery infected with *Sclerotinia sclerotiorum.* Appl. Microbiol. 23(1): 852-856.

Zervoudakis, N., N. Tairis, G. Salahas and C.D. Georgiou. 2003. Pcarotene production and sclerotial differentiation in *Sclerotinia minor.* Mycol. Res. 107(5): 624-631.

PMRA 1094853 Origin, Derivation and Identification of *Sclerotinia minor* strain IMI344141. DACO M2.7.1

PMRA 1094854 SARRITOR Phenotypic Characterization. DACO M2.7.1.

PMRA 1094858 Biological Properties of *Sclerotinia minor*. DACO M2.7.2.

PMRA 1094859 Susceptibility of Cool Season Turf Grass Species to *Sclerotinia minor* (IMI344141) Barley-Based Formulation. DACO M2.7.2.

PMRA 1094860 Effect of SARRITOR(*Sclerotinia minor*) on Germination and Emergence of Turfgrass. DACO M2.7.2.

PMRA 1094861 Manufacturing Methods and Quality Assurance; Manufacturing Protocol and Standard Operating Procedures for *Sclerotinia minor* Jagger. DACO M2.8.

PMRA 1094862 Quality Assurance (QA) Assays for the *Sclerotinia minor* (IMI344141) Barley-Based Formulation. DACO M2.8.

PMRA 1094863 Potency Estimation and Product Guarantee. DACO M2.9.2.

PMRA 1094844 Unintentional Ingredients. DACO M2.9.3.

## 3.0 Impact on Human and Animal Health

PMRA 1094855 Toxicology Summary. DACO M4.1.

PMRA 1094856 Summary of In-effectivity and Toxicity. DACO M4.2.1.

PMRA 1094857 Acute Oral Toxicity/Pathogenicity Study of Sarritor (TGAI) in Sprague-Dawley Rats. DACO M4.2.2.

PMRA 1094864 Request for waiver for oral in-effectivity study. DACO M4.2.2.

PMRA 1094865 Acute Pulmonary Toxicity Study of Sarritor (TGAI) in Sprague-Dawley Rats. DACO M4.2.3.

PMRA 1094866 Request for waiver for acute pulmonary in-effectivity study. DACO M4.2.3.

PMRA 1315262 Response to Request for Clarification on PMRA# 1094864 "Acute Pulmonary Toxicity Study of Sarritor (TGAI) in Sprague-Dawley Rats." DACO M4.2.3.

PMRA 1094867 Summary. DACO M4.3.1.

PMRA 1094868 Acute Intra peritoneal Toxicity/Pathogenicity Study of Sarritor (TGAI) in Sprague-Dawley Rats. DACO M4.3.3.

PMRA 1315274 Raw Observation Data Report for 19-Jul-2005 to 09-Aug-2005 for "Acute Intra peritoneal Toxicity/Pathogenicity Study of Sarritor (TGAI) in Sprague-Dawley Rats." DACO M4.3.3.

PMRA 1094869 Acute Dermal Toxicity/Irritation/Pathology Study of Sarritor (Milled End Product) in New Zealand Albino Rabbits. DACO M4.5.2.

PMRA 1094870 Summary. DACO M4.5.1

PMRA 1094871 Summary of Hypersensitivity Findings. DACO M4.6.

PMRA 1094872 Summary of Genotoxicity Potential. DACO M4.8.

PMRA 1094880 Acute Eye Irritation/Corrosion Study of Sarritor (Milled End Product) in New Zealand Albino Rabbits. DACO M4.9.

PMRA 1094881 Published References (7) Cited in M4. DACO M4.9.

Afek, U., N. Aharoni and S. Carmeli. 1995. The involvement of marmesin in celery resistance to pathogens during storage and the effect of temperature on its concentration. Am. Phytopath. Soc. 85(9): 1033-1036.

Afek, U., J. Orenstein and N. Aharoni. 2002. The involvement of marmesin and its interaction with GA3 and psoralens in parsley decay resistance. Can. J. Plant Pathol. 24: 61-64.

Austed, J. and G. Kavli. 1983. Photoxic dermatitis caused by celery infected with *Sclerotinia sclerotiorum.* Contact Dermatitis. 9:448-451.

Beier, R.C. and E.H. Oertli. 1983. Psoralen and other liner furocoumarins as phytolexins in celery. Phytochem. 22(11): 2595-2597.

Heath-Pagliuso, S., S.A. Matlin, N. Fang, R.H. Thompson and L. Rappaport. 1992. Stimulation of furanocoumarin accumulation in celery and celeriac tissues by *Fusarium oxysporum* F. SP. *MIL* Phytochem. 3l(8): 2683-2688.

Schell, L.D., V.B. Perone, R.L. Larkin and R.E. Kupel. 1963. The isolation and characterization of two phytotoxic furanocoumarins (psoralens) from diseased celery. Biochem. 2(5):1127-1131.

Wu, C.M., P.E. Koehler and J.C. Ayres. 1972. Isolation and identification of xanthotoxin (8-methoxypsoralen) and bergapten (5-methoxypsoralen) from celery infected with *Sclerotinia sclerotiorum.* Appl. Microbiol. 23(1):852-856.

## 4.0 Impact on the Environment

PMRA 1094882 Summary. DACO M8.1

PMRA 1094883 Greenhouse Studies. DACO M8.3

PMRA 1094873 Field Studies. DACO M8.4

PMRA 1094874 Published References (8) Cited in M8. DACO M8.5

PMRA 1094875 Summary. DACO M9.1

PMRA 1094876 Sarritor (TGAI): An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite. DACO M9.2.1

PMRA 1094877 Request for waiver for toxicity/pathogenicity on wild mammals. DACO M9.3

PMRA 1094878 Sarritor (TGAI): A Five-Concentration Toxicity and Pathogenicity Test with the Rainbow Trout (*Onchorynchus mykiss*). DACO M9.4.1

PMRA 1094879 Sarritor (TGAI): A Dietary Pathogenicity and Toxicity Study with the Honeybee (*Apis mellifera*). DACO M9.5.1

PMRA 1094884 Request for waiver for toxicity/pathogenicity testing of additional terrestrial arthropods. DACO M9.5.1

PMRA 1094885 Sarritor (TGAI): A 21-Day Life Cycle Toxicity and Pathogenicity Test with the Cladoceran (*Daphnia magna*) DACO M9.5.2

PMRA 1094886 Sarritor (EP): An Acute Toxicity Study with the Earthworm in an Artificial Substrate. DACO M9.6

PMRA 1094887 Request for waiver for testing terrestrial plant species. DACO M9.8.1

PMRA 1094888 Susceptibility of Cool Season Turf Grass Species to *Sclerotinia minor* (IMI344141) Barley-Based Formulation. DACO M9.8.1

PMRA 1094889 Susceptibility of Cool Season Turf Grass Species to *Sclerotinia minor* (IMI344141) Barley-Based Formulation. DACO M9.8.1

PMRA 1094890 Sarritor (EP): A 7-Day Toxicity Study with Duckweed (Lemna gibba G3). DACO M9.8.2

PMRA 1094891 Request for waiver for testing of additional aquatic plant species. DACO M9.8.2

PMRA 1094892 Published References (6) Cited in M9. DACO M9.9

Anas, O. and R.D. Reeleder. 1987. Recovery of fungi and arthropods from Sclerotia of *Sclerotinia sclerotiorum* in Quebec muck soils. Phytopath. 77(2):327-330.

Anas, O. and R.D Reeleder. 1988. Consumption of sclerotia of *Sclerotinia sclerotiorum* by larvae of *Bradysia coprophilu*: influence of soil factors and interations between larvae and *Trichoderma viride*. Soil Biol. Biochem. 20(5):619-624.

Coley-Smith, J.R. and R.C. Cooke. 1971. Survival and germination of fungal sclerotia. Annu. Rev. Phytopathol. 9:65-92.

Hollowell, .E. and B.B. Shew. 2001. Yellow nutsedge *(Cyperus esculentus* L.) as a host for *Sclerotinia minor*. Plant Dis. 85(5):562.

Hollowell, J.E., B.B. Shew, M.A. Cubeta and J.W. Wilcut. 2003. Weed species as hosts of *Sclerotinia minor* in peanut fields. Plant Dis. 87(2): 197-199.

Melzer, M.S., E.A. Smith and Boland, G.J. 1997. Index of plant hosts of *Sclerotinia minor*. Can. J. Plant Path. 19:272-280.

**5.0 Value**

PMRA 1094911 International regulatory status of Sclerotinia minor (IMI 344141) and Sarritor. Document ID: M1.3. Nov. 2005. 4260864 Canada Inc. pp 1.

PMRA 1094894 Effect of turfgrass mowing height on bio-control of dandelion with *Sclerotinia minor* . Report ID BST-01. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 37.

PMRA 1094895 Effect of host plant age and turfgrass competition on the efficacy of Sarritor as a bio-control agent of dandelion (*Taraxacum officinale*). Report ID PR-SM-013. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 10

PMRA 1094896 Collaborative field efficacy trials with isolates of *Sclerotinia minor*. Report ID 1996-01. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 7.

PMRA 1094897 Collaborative field efficacy trials with Sarritor (*Sclerotinia minor* IMI 344141). Report Number 1997-01. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 6.

PMRA 1094898 Collaborative field efficacy trials with Sarritor (*Sclerotinia minor* IMI 344141). Report Number 1998-01. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 8.

PMRA 1094899 Reduced rate efficacy trials. Report Number 2004-01. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 6.

PMRA 1094900 Dose response and formulation. Report Number 2004-01. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 4.

PMRA 1094906 Dandelion growth stage experiment with Sarritor (*Sclerotinia minor* IMI 344141). Report Number 1998-02. Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 3.

PMRA 1094907 Control of dandelion by Sarritor (*Sclerotinia minor* IMI 344141) and re-growth potential of treated plants. Report Number PR-SM-012.

Document ID: M10.2.2. Nov. 2005. Department of Plant Science, McGill University. pp 10.

PMRA 1094901 Phytotoxicity and phyto-pathogenicity. Document ID: M10.3.1. Nov. 2005. Department of Plant Science, McGill University. pp 8.

PMRA 1094902 Comparability with crop protection and management practices. Document ID: M10.3.2. Nov. 2005. Department of Plant Science, McGill University. pp 4.

PMRA 1094903 Profile of the EP. Document ID: M10.4.1. Nov. 2005. Department of Plant Science, McGill University. pp 3.

PMRA 1094904 Nature and economics of pest problem in Canada. Document ID: M10.4.2. Nov. 2005. MP Stewart and Associates. pp 3.

PMRA 1094905 Current crop protection tolls and practices. Document ID: M10.4.3. Nov. 2005. MP Stewart and Associates. pp 3.

PMRA 1094908 Contribution to IPM strategies and practices. Document ID: M10.4.4. Nov. 2005. MP Stewart and Associates. pp 3.

PMRA 1094909 Published References (10) Cited in M10

Abawi, G.S. and R.G. Grogan, 1979. Epidemiology of diseases caused by *Sclerotinia* species. Phytopath. 69(8):899-904.

List of widely prevalent plant pathogenic fungi: widely prevalent fungi list 2001, APHIS, USDA.

Farr, D.F. *et al.* Fungi on plants and plant products in the United States. Am. Phytopath. Soc. Sclerotium-941.

Ginns, J.H, 1986. Compendium of plant disease and decay fungi in Canada 1960-1980. Agriculture Canada Pub. 1813.

Jarvis, W.R. 1985. *Sclerotinia minor* as the cause of lettuce drop in southwestern Ontario. Can. Plant Disease Survey 65:1.

Kohn, L.M. *et al.* 1991. Mycelia incompatibility and molecular markers identify genetic variability in field populations of *Sclerotinia sclerotiorum*. Phytopath. 81(4):480-485.

Kora, C. and G.J. Bowland. 2002. First report of foliar and root infection of carrot by *Sclerotinia minor* in Ontario, Canada. Plant Disease. 86(2).

Melzer, M.S. *et al.* 1997. Index of plant hosts of *Sclerotinia minor*. Can. J. Plant Path. 19:272-280.

Porter, D.M. and M.K. Beute, 1974. Sclerotinia blight of peanuts. Phytopath. 64:263-264.

Toms, H.N.W. 1964. Plant disease of southern British Columbia - a host index. Can. Plant Disease Survey. 44:143/180.